

Demographics

*** Required fields**

* Name of Site: _____

* Type of Visit: _____

e.g. Screening, Baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months.

* Date of Visit: _____

* GUID: _____

* Age of Subject (years and months): _____

Subject ID: _____

***1) Gender:** ☐ Female ☐ Male ☐ Unspecified ☐ Unknown

***2) Ethnicity:** "The category of ethnicity you most closely identify with?"

☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not reported

***3) Race ("X" those with which you identify):**

- ☐ American Indian/Alaska Native
- ☐ African - Black (i.e., south of the Sahara)
- ☐ African - North (i.e., Sahara or north of the Sahara: e.g., Algeria, Egypt, Morocco, Tunisia, etc.)
- ☐ American - Black (i.e., people of African descent whose area of origin is within the Americas: e.g., Canada, Caribbean, Brazil, US, etc.)
- ☐ Asian - East (i.e., China, Japan, Korea, etc.)
- ☐ Asian - West (i.e., Bangladesh, India, Iran, Iraq, Pakistan, etc.)
- ☐ Caucasian (e.g., British Isles, Germany, Peninsular Spain, Latin America, France, Italy, Ireland, Sweden, etc.)
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Unknown or Not reported
- ☐ Other (i.e., if none of the above categories reflects your area of origin, then specify as precisely as possible)

***4) Education Level (select the highest level attained):**

- | | | |
|--|-------------------------------------|-------------------------------------|
| <input type="checkbox"/> Never attended/ Kindergarten only | <input type="checkbox"/> 1st Grade | <input type="checkbox"/> 2nd Grade |
| <input type="checkbox"/> 3rd Grade | <input type="checkbox"/> 4th Grade | <input type="checkbox"/> 5th Grade |
| <input type="checkbox"/> 6th Grade | <input type="checkbox"/> 7th Grade | <input type="checkbox"/> 8th Grade |
| <input type="checkbox"/> 9th Grade | <input type="checkbox"/> 10th Grade | <input type="checkbox"/> 11th Grade |

- | | | |
|--|---|--|
| <input type="checkbox"/> 12th Grade, no diploma | <input type="checkbox"/> High school graduate | <input type="checkbox"/> GED or equivalent |
| <input type="checkbox"/> Some college, no degree | <input type="checkbox"/> Associate degree: occupational, technical, or vocational program | |
| <input type="checkbox"/> Associate degree: academic program | <input type="checkbox"/> Bachelor's degree (e.g., BA, AB, BS, BBA) | |
| <input type="checkbox"/> Master's degree (e.g., MA, MS, MEng, MEd, MBA) | | |
| <input type="checkbox"/> Professional school degree (e.g., MD, DDS, DVM, JD) | | |
| <input type="checkbox"/> Doctoral degree (e.g., PhD, EdD) | | |
| <input type="checkbox"/> Unknown | | |

***5) Employment status:**

- ☐ Working now
- ☐ Only temporarily laid off, sick leave, or maternity leave
- ☐ Looking for work, unemployed
- ☐ Retired
- ☐ Disabled, permanently or temporarily
- ☐ Keeping house
- ☐ Student
- ☐ Unknown
- ☐ Other, please specify _____

GENERAL INSTRUCTIONS

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as supplemental if a study requires that level of detail, otherwise the NIH standard should be used as the minimum standard.

Important note: Four of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all Parkinson's disease clinical studies to collect). The remaining data element is classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

Responses to the demographic elements should be obtained from self-report when possible.

- **Date of birth** – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
- **Sex** – Choose one. Response is obtained by report of the participant/subject or caretaker
- **Ethnicity** – Choose only one with which the participant/ subject most closely identifies.
- **Race** – Choose all those with which the participant/ subject identifies.
- **Education Level** – Choose only one, the highest level of education the participant/subject has attained.